

HHS Issues Report on Antipsychotic Drug Use in Nursing Homes

Atlanta Hospital News

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June 16, 2011

The Department of Health and Human Services (“HHS”) issued a report in May of 2011 documenting concerns with the use of atypical antipsychotic drugs in nursing homes. The report found that fourteen percent (14%) percent of nursing home residents had Medicare claims for these drugs, and that fifty-one percent (51%) of the claims were erroneous. The claimed drugs were either not used for medically accepted indications or not documented as having been administered to the elderly nursing home residents.

The report also found that the atypical antipsychotic drugs were often prescribed for uses that are not approved by the Food and Drug Administration (the “FDA”) and do not qualify as for Medicare coverage. According to the report, eighty-eight percent (88%) of the time these drugs were prescribed for elderly patients with dementia, a population that the FDA has warned faces an increased risk of death from this class of drugs. For atypical antipsychotics, the FDA imposes its strongest safety warning, often called a "black box warning," emphasizing an increased risk of death when used in elderly people with dementia. Physicians can use their medical judgment to prescribe drugs for uses unapproved by the FDA, including to patients for whom the boxed warning applies.

The report also found that for one in five residents, nursing homes dispensed these drugs in a way that violated the government's standards for their use. For example, the prescribed dose was too high or residents were on medication for too long.

HHS initiated the report after Senator Charles Grassley questioned how many nursing home residents received a class of antipsychotic drugs introduced in the 1990s, among them risperidone and olanzapine. These drugs, known as "atypical" or "second generation" antipsychotics, replaced (at much higher cost) antipsychotic drugs introduced in the 1950s and 1960s to treat schizophrenia.

Atypical antipsychotic drug use by elderly nursing home patients has been an issue in recent law enforcement activities. In 2009 and 2010, Omnicare, Inc. settled with the U.S. Department of Justice for \$98 million to resolve allegations that it received kickbacks to recommend drugs, including Risperdal, for use in nursing homes. In a separate suit, Risperdal also settled allegations that it paid kickbacks to Omnicare for recommending Risperdal in for use in nursing homes.

Additionally, Eli Lilly pled guilty to criminal charges associated with illegally marketing its drug Zyprexa (olanzapine), including to doctors that treat elderly nursing home patients. Several other pharmaceutical companies -- Bristol-Meyers Squibb, Astra Zeneca and Pfizer -- settled government allegations that they improperly promoted their antipsychotic drugs for unapproved uses.

The Centers for Medicare and Medicaid Services (“CMS”) commented on the report, stating that it believes the root cause of the issue is the contractual arrangements involving long-term care (“LTC”) facilities, LTC pharmacies, LTC consultant pharmacists and pharmaceutical manufacturers and/or distributors and the incentives such arrangements provide.

Medicare covers atypical antipsychotic drugs for Medicare beneficiaries in nursing homes under Medicare Part D and Part B. For drugs to qualify for Medicare Part D reimbursement, the drugs must be used for medically accepted indications. These indications include both the FDA-approved uses, and off-label uses which are supported by one of three compendia: *The American Hospital Formulary Service Drug Information*; *the U.S. Pharmacopeia-Drug Information*; *the DrugDEX Information System*.

“To solve this problem, everyone has a role to play” stated Daniel R. Levinson, Inspector General for the HHS. He continued, “Nursing homes and pharmacies that serve the elderly should base drug-dispensing decisions on the best interest of the patient, not on improper influence of drug companies....[and] Government must uphold patient safety standards established for nursing homes and combat off-label promotion of these powerful and potentially lethal drugs.”

This report is not only a sign of what new investigations the Inspector General may initiate, but this report could lead to a slew of new malpractice cases. Hospitals in Georgia that own, operate, or are affiliated with nursing homes should use this opportunity to review its practices and contracts with pharmaceutical companies, as well as take steps to re-educate physicians on the importance of independence from pharmaceutical companies.